Defining Occupational and Consumer Exposure Limits for Nanomaterials - First Experiences from REACH Registrations

Abstract:
By 1 December 2010 substances manufactured or imported in the EU ≥ 1000 t (as well as certain other substances) had to be registered under the REACH Regulation 1907/2006. The Joint Research Centre (JRC) in close cooperation with the European Chemicals Agency (ECHA) carried out an analysis and assessment of what type of information on nanomaterials was provided in the received registrations. The aim of the assessment was to develop options for an adaptation of the REACH regulation to ensure proper information generation and reporting and an appropriate risk/safety assessment of nanomaterials (Nano Support project). It should be noted that this analysis and assessment was not a compliance check of the dossiers. From 26000 submitted registration dossiers covering 4700 substances finally 25 dossiers (19 substances) were identified to cover nanomaterials or nanoforms of a substance. It is possible that other dossiers are considered to cover nanomaterials or nanoforms by the registrants, however such dossiers could not be identified to address nanoforms given the information contained in those dossiers. The identified 25 dossiers were subject to a detailed analysis and assessment of information provided for all endpoints including substance identity, physico-chemical properties, human health, environmental fate & behaviour, ecotoxicity, PBT assessment, Classification and Labelling as well as the attached Chemical Safety Report documenting the Chemical Risk/Safety Assessment. In order to evaluate how the safety of workers and consumers was ensured, it was appropriate to check how the "Derived No (Minimum) Effect Levels" (DN(L)ELs) were established for substances, covering nanomaterials or nanoforms. DNELs were established mainly for long term inhalation exposure of workers. Half of the assessed dossiers included an oral long term DNEL for the general population. DNELs were usually not specific for nanosized forms and, in the few cases where they were calculated for nanosized materials, they were not derived from hazard data for the nanoform. Different methods for deriving the DNELs were applied and few dossiers derived DNELs by applying the default assessment factors in the REACH guidance.. Several DNELs were based on available Occupational Exposure Limits (OELs) for inhalable and respirable dust or the nuisance dust levels, which have not been established for nanosized materials. In general lower (i.e. less strict) assessment factors were applied with different types of justification. All DNELs were expressed in the mass metrics. It is important to note that submission, identification and selection of the dossiers addressed in this study was done before the adoption of the EC recommendation (2011/696/EU) on a definition of nanomaterial and before the publication of the revised ECHA guidance documents that include recommendations for nanomaterials.